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Attorneys for Defendant

Watson Laboratories, Inc. - Florida

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

| | | |
|--------------------------------------|---|-----------------------------------|
| WARNER CHILCOTT COMPANY, LLC and |) | |
| WARNER CHILCOTT (US), LLC, |) | |
| Plaintiffs, |) | |
| v. |) | Civil Action No. 11-5989 (FSH/PS) |
| WATSON LABORATORIES, INC. - FLORIDA, |) | |
| Defendant. |) | |

**DEFENDANT WATSON LABORATORIES, INC. - FLORIDA's
ANSWER, AFFIRMATIVE DEFENSES, AND
COUNTERCLAIMS TO PLAINTIFFS' AMENDED COMPLAINT**

Defendant Watson Laboratories, Inc. – Florida (“Watson Florida”) submits the following Answer, Affirmative Defenses and Counterclaims to Plaintiffs’ Amended Complaint (“Amended Complaint”). This Answer is based upon Watson Florida’s knowledge as to its own activities and upon information and belief as to the activities of others. The numbered paragraphs below correspond to the paragraphs in the Amended Complaint.

AS TO THE ALLEGED PARTIES

1. Watson Florida admits the allegations contained in Paragraph 1.
2. Watson Florida admits the allegations contained in Paragraph 2.
3. Watson Florida admits the allegations contained in Paragraph 3.
4. Watson Florida admits that it is in the business of developing and manufacturing generic pharmaceutical products for the United States market. Watson Florida denies the remaining allegations of this paragraph.
5. Watson Florida admits the allegations contained in Paragraph 5.

AS TO THE ALLEGED JURISDICTION AND VENUE

6. Watson Florida admits that this action arises under the patent laws of the United States, and that this Court has jurisdiction over the claims against Watson Florida under 28 U.S.C. §§ 1331 and 1338(a).
7. Watson Florida will not contest personal jurisdiction in this Court for purposes of this action only. Watson Florida denies the remaining allegations of this paragraph.
8. Watson Florida will not contest personal jurisdiction in this court for the purposes of this action only. Watson Florida denies the remaining allegations of this paragraph.
9. Watson Florida will not contest personal jurisdiction in this court for the purposes of this action only. Watson Florida denies the remaining allegations of this paragraph.

10. Watson Florida will not contest personal jurisdiction in this court for the purposes of this action only. Watson Florida denies the remaining allegations of this paragraph.

11. Watson Florida will not contest personal jurisdiction in this court for the purposes of this action only. Watson Florida denies the remaining allegations of this paragraph.

12. Watson Florida will not contest venue in this Court for purposes of this action only. Watson Florida denies the remaining allegations of this paragraph.

AS TO THE ALLEGED BACKGROUND

13. Watson Florida lacks knowledge or information sufficient to form a belief about the truth of the allegations of this paragraph and therefore denies them.

14. Watson Florida admits that United States Patent No. 7,645,459 (“the ‘459 patent”) is entitled “Dosage Forms of Bisphosphonates,” was issued on or about January 12, 2010, and is attached to the Complaint as Exhibit A. Watson Florida denies the remaining allegations of this paragraph.

15. Watson Florida admits that United States Patent No. 7,645,460 (“the ‘460 patent”) is entitled “Dosage Forms of Risedronate,” was issued on or about January 12, 2010, and is attached to the Complaint as Exhibit B. Watson Florida denies the remaining allegations of this paragraph.

16. Watson Florida admits that United States Patent No. 8,246,989 (“the ‘989 patent”) is entitled “Dosage Forms of Risedronate,” was issued on or about January 12, 2010, and is attached to the Complaint as Exhibit C. Watson Florida denies the remaining allegations of this paragraph.

17. Watson Florida lacks knowledge or information sufficient to form a belief about the truth of the allegations of this paragraph and therefore denies them.

18. Watson Florida admits that the ‘459, ‘460, and ‘989 patents have been listed in the *FDA Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange

Book") for Atelvia®, and lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of this paragraph and therefore denies them.

19. Watson Florida admits that it submitted an ANDA that contains a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of Risedronate Sodium Delayed-release Tablets before the expiration of the '459, '460, and '989 patents.

AS TO THE ALLEGED COUNT I
(CLAIM FOR INFRINGEMENT OF THE '459 PATENT)

20. Watson Florida restates and incorporates by reference its responses to the allegations of paragraphs 1-19 as though fully set forth herein.

21. Watson Florida admits that ANDA No. 20-3090 included a 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certification ("Paragraph IV Certification") certifying that the '459 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in ANDA No. 20-3090. Watson Florida denies the remaining allegations of this paragraph.

22. Watson Florida admits that it sent a letter to Warner Chilcott dated August 29, 2011. The August 29, 2011 letter speaks for itself. Watson Florida lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of this paragraph and therefore denies them.

23. Watson Florida denies the allegations contained in Paragraph 23.

24. Watson Florida denies the allegations contained in Paragraph 24.

25. Watson Florida denies the allegations contained in Paragraph 25.

26. Watson Florida denies the allegations contained in Paragraph 26.

AS TO THE ALLEGED COUNT II
(CLAIM FOR INFRINGEMENT OF THE '460 PATENT)

27. Watson Florida restates and incorporates by reference its responses to the allegations of paragraphs 1-19 as though fully set forth herein.
28. Watson Florida admits that ANDA No. 20-3090 included a 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certification (“Paragraph IV Certification”) certifying that the ‘460 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in ANDA No. 20-3090. Watson Florida denies the remaining allegations of this paragraph.
29. Watson Florida admits that it sent a letter to Warner Chilcott dated August 29, 2011. The August 29, 2011 letter speaks for itself. Watson Florida lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of this paragraph and therefore denies them.
30. Watson Florida denies the allegations contained in Paragraph 30.
31. Watson Florida denies the allegations contained in Paragraph 31.
32. Watson Florida denies the allegations contained in Paragraph 32.
33. Watson Florida denies the allegations contained in Paragraph 33.

AS TO ALLEGED COUNT III
(CLAIM FOR INFRINGEMENT OF THE '989 PATENT)

34. Watson Florida restates and incorporates by reference its responses to the allegations of paragraphs 1-19 as though fully set forth herein.
35. Watson Florida admits that ANDA No. 20-3090 included a 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certification (“Paragraph IV Certification”) certifying that the ‘989 patent

is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in ANDA No. 20-3090. Watson Florida denies the remaining allegations of this paragraph.

36. Watson Florida denies the allegations contained in Paragraph 36.

37. Watson Florida denies the allegations contained in Paragraph 37.

AS TO PLAINTIFFS' ALLEGED PRAYER FOR RELIEF

(a) Watson Florida denies that Plaintiffs are entitled to the relief requested in paragraph (a).

(b) Watson Florida denies that Plaintiffs are entitled to the relief requested in paragraph (b).

(c) Watson Florida denies that Plaintiffs are entitled to the relief requested in paragraph (c).

(d) Watson Florida denies that Plaintiffs are entitled to the relief requested in paragraph (d).

(e) Watson Florida denies that Plaintiffs are entitled to the relief requested in paragraph (e).

(f) Watson Florida denies that Plaintiffs are entitled to the relief requested in paragraph (f).

(g) Watson Florida denies that Plaintiffs are entitled to the relief requested in paragraph (g).

(h) Watson Florida denies that Plaintiffs are entitled to the relief requested in paragraph (h).

(i) Watson Florida denies that Plaintiffs are entitled to the relief requested in paragraph (i).

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations found in the Complaint not otherwise admitted, Watson Florida avers and asserts the following defenses:

FIRST SEPARATE DEFENSE

(Noninfringement)

The manufacture, use, sale, offer for sale, or importation of the risedronate sodium delayed release products that are the subject of ANDA No. 20-3090 have not, do not and would not infringe any valid and enforceable claim of the '459, '460 or '989 patents either directly or indirectly, literally or under the doctrine of equivalents.

SECOND SEPARATE DEFENSE

(Invalidity)

The claims of the '459, '460, and '989 patents are invalid for failure to comply with one or more of the provisions of the United States Code, including, but not limited to 35 U.S.C. §§ 102, 103 and/or 112.

THIRD SEPARATE DEFENSE

(Failure to State a Claim)

The Amended Complaint is subject to dismissal for failure to state a claim upon which relief may be granted.

FOURTH SEPERATE DEFENSE

(Other Defenses)

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Watson Florida, for its Counterclaims against Plaintiffs Warner Chilcott Company, LLC and Warner Chilcott (US), LLC (collectively “Plaintiffs”), alleges as follows:

PARTIES

1. Counterclaimant Watson Florida is a Florida Corporation having a principal place of business at 4955 Orange Drive, Davie, Florida 33314.
2. Counterclaim Defendant Warner Chilcott Company, LLC is a limited liability company organized and existing under the laws of Puerto Rico, having offices at Union Street, Road 195, Km. 1.1, Fajardo, Puerto Rico.
3. Counterclaim Defendant Warner Chilcott (US), LLC is a limited liability company established under the laws of the state of Delaware with offices at 100 Enterprise Drive, Rockaway, NJ 07866.

JURISDICTION AND VENUE

4. This is a declaratory judgment action under the patent laws of the United States, 35 U.S.C. § 1, *et seq.* Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).
5. This Court has personal jurisdiction over Plaintiffs because, on information and belief, Plaintiffs are actively and regularly engaged in business in the State of Delaware and derive substantial revenues from things used or consumed in the State of Delaware and because Warner Chilcott (US), LLC is a Delaware limited liability company.
6. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and 1400(b). This Court may declare the rights and legal relation of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(e)(5).

BACKGROUND

7. Warner Chilcott Company, LLC is the owner of the '459, '460 and '989 patents.
8. Warner Chilcott (US), LLC is the holder of New Drug Application ("NDA") No. 22-560.
9. The '459, '460, and '989 patents are listed in the Orange Book with respect to the Atelvia® drug product that is the subject of Plaintiffs' Complaint.
10. Watson Florida filed ANDA No. 20-3090 with the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) seeking FDA approval to market Risedronate Sodium Delayed-release Tablets that are the subject of the ANDA in the United States. ANDA No. 20-3090 included a 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certification ("Paragraph IV Certification") certifying that the proposed ANDA product will not infringe any valid and enforceable claim of the '459 or '460 patents, and now includes an amendment with a Paragraph IV Certification to the '989 patent.

11. In accordance with 21 U.S.C. § 355(j)(2)(B), Watson Florida sent a letter to Plaintiffs with a notification that it had filed ANDA No. 20-3090 with a Paragraph IV Certification stating that Watson Florida's proposed Risedronate Sodium Delayed-release Tablets do not infringe any valid and enforceable claims of the '459 or '460 patents.

12. In accordance with 21 U.S.C. § 355(j)(2)(B), Watson Florida sent a letter to Plaintiffs with a notification that it had filed an amendment to ANDA No. 20-3090 with a Paragraph IV Certification stating that Watson Florida's proposed Risedronate Sodium Delayed-release Tablets do not infringe any valid and enforceable claims '989 patent.

13. On or about October 12, 2011, Plaintiffs filed a Complaint for patent infringement alleging that Watson Florida's submission of ANDA No. 20-3090 infringes the '459 and '460 patents under 35 U.S.C. §271(e)(2)(A).

14. On or about September 11, 2012, Plaintiffs filed an Amended Complaint for patent infringement alleging that Watson Florida's submission of ANDA No. 20-3090 infringes the '459, '460, and the '989 patents under 35 U.S.C. §271(e)(2)(A).

15. A definite and concrete, real and substantial, justiciable controversy exists between Plaintiffs and Watson Florida with respect to the validity and infringement of the '459, '460, and '989 patents, which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

FIRST COUNT

(Declaratory Judgment of Noninfringement of the '459 Patent)

16. Watson Florida restates and incorporates by reference the allegations set forth in paragraphs 1-15 of this Counterclaim as though fully set forth herein.

17. Watson Florida will not directly, indirectly, contributorily, and/or by inducement infringe either literally or under the doctrine of equivalents any valid and enforceable claim of the '459 patent under 35 U.S.C. § 271 either by the manufacture, use, or sale in the United States of proposed Risedronate Sodium Delayed-release Tablets that are the subject of ANDA No. 20-3090, or by meaningful preparation to manufacture, use, market, or sell in the United States proposed Risedronate Sodium Delayed-release Tablets that are the subject of ANDA No. 20-3090.

SECOND COUNT

(Declaratory Judgment of Invalidity of the '459 Patent)

18. Watson Florida restates and incorporates by reference the allegations set forth in paragraphs 1-15 as though fully set forth herein.

19. Based at least upon the facts, circumstances, prior art, and argument set forth in Watson Florida's New Jersey Patent Local Rule 2.2 disclosures, served on May 2, 2012 and designated at Highly Confidential–Outside Counsel Only, the claims of the '459 patent are invalid for failure to comply with one or more of the provisions of the United States Code, including, but not limited to 35 U.S.C. §§ 102, 103 and/or 112.

THIRD COUNT

(Declaratory Judgment of Noninfringement of the '460 Patent)

20. Watson Florida restates and incorporates by reference the allegations set forth in paragraphs 1-17 as though fully set forth herein.

21. Watson Florida will not directly, indirectly, contributorily, and/or by inducement infringe either literally or under the doctrine of equivalents any valid and enforceable claim of the '460 patent under 35 U.S.C. § 271 either by the manufacture, use, or sale in the United States of proposed Risedronate Sodium Delayed-release Tablets that are the subject of ANDA No. 20-3090, or by meaningful preparation to manufacture, use, market, or sell in the United States proposed Risedronate Sodium Delayed-release Tablets that are the subject of ANDA No. 20-3090.

FOURTH COUNT

(Declaratory Judgment of Invalidity of the '460 Patent)

22. Watson Florida restates and incorporates by reference the allegations set forth in paragraphs 1-19 as though fully set forth herein.

23. Based at least upon the facts, circumstances, prior art, and argument set forth in Watson Florida's New Jersey Patent Local Rule 2.2 disclosures, served on May 2, 2012 and designated at Highly Confidential –Outside Counsel Only, the claims of the '460 patent are invalid for failure to comply with one or more of the provisions of the United States Code, including, but not limited to 35 U.S.C. §§ 102, 103 and 112.

FIFTH COUNT

(Declaratory Judgment of Noninfringement of the '989 Patent)

24. Watson Florida restates and incorporates by reference the allegations set forth in paragraphs 1-17 as though fully set forth herein.

25. Watson Florida will not directly, indirectly, contributorily, and/or by inducement infringe either literally or under the doctrine of equivalents any valid and enforceable claim of the '989 patent under 35 U.S.C. § 271 either by the manufacture, use, or sale in the United States of proposed Risedronate Sodium Delayed-release Tablets that are the subject of ANDA No. 20-3090, or by meaningful preparation to manufacture, use, market, or sell in the United States proposed Risedronate Sodium Delayed-release Tablets that are the subject of ANDA No. 20-3090.

SIXTH COUNT

(Declaratory Judgment of Invalidity of the '989 Patent)

26. Watson Florida restates and incorporates by reference the allegations set forth in paragraphs 1-19 as though fully set forth herein.

27. Upon information and belief, the claims of the '989 patent are invalid for failure to comply with one or more of the provisions of the United States Code, including, but not limited to 35 U.S.C. §§ 102, 103 and 112.

PRAYER FOR RELIEF

WHEREFORE, Watson Florida respectfully requests that the Court enter an order:

- A. Dismissing the Complaint with prejudice;
- B. Declaring that Watson Florida's proposed Risedronate Sodium Delayed-release Tablets that are the subject of ANDA No. 20-3090 will not directly, indirectly, contributorily, and/or by inducement infringe either literally or under the doctrine of equivalents any valid and enforceable claim of the '459 or '460 patents under 35 U.S.C. § 271;
- C. Declaring that the claims of the '459, '460, and '989 patents are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 102, 103 and/or 112;
- D. Declaring this case exceptional and awarding Watson Florida reasonable attorneys' fees and costs under 35 U.S.C. § 285; and
- E. Awarding Watson Florida its costs;
- F. Awarding Watson Florida such other further relief as the Court deems just and equitable.

Dated: September 28, 2012.

Respectfully submitted,

**SAIBER LLC
Attorneys for Defendant Watson
Laboratories, Inc.- Florida**

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